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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/565,789 | 01/25/2006 | Dinesh Narendra Rele | HM/15-22928/A/PCT | 7615 |

324 7590 06/23/2008
JoAnn Villamizar
Ciba Corporation/Patent Department
540 White Plains Road
P.O. Box 2005
Tarrytown, NY 10591

| EXAMINER | |
|---|---|
| YOUNG, SHAWQUIA | |
| ART UNIT | PAPER NUMBER |
| 1626 | |
| MAIL DATE | DELIVERY MODE |
| 06/23/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/565,789 | RELE ET AL. | |
| | Examiner | Art Unit | |
| | SHAWQUIA YOUNG | 1626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,8-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-6,18 and 19* is/are allowed.

6)☒ Claim(s) *8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Claims 1-6, 8-16, 18 and 19 are currently pending in the instant application. Applicants have amended claims 1 and 8 in an amendment filed on March 14, 2008.

## I. *Response to Arguments/Remarks*

Applicants' amendment, filed on March 14, 2008, has overcome the rejection of claims 1-6, 18 and 19 under 35 USC 112, second paragraph as being unclear. The rejection has been withdrawn.

The Examiner has rejoined the process claims 8-16 for examination.

## II. *Rejection(s)*

### *Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for the antimicrobial treatment of surfaces wherein the bacteria, yeast or fungi is *staphylococcus aureus*, *staphylococcus*, *corynebacterium xerosis*, *c. minutissimum*, *propionbacterium acnes*, *E. coli*, *proteus vulgaris*, *kiebsiella pneumoniae*, *salmonella choleraesuis*, *pseudomonas aeruginosa*,

*candida albicans* or *aspergillus niger* does not reasonably provide enablement for the antimicrobial treatment of surfaces against all types of microbial agents. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case,

***The nature of the invention***

The nature of the invention is the antimicrobial treatment of surfaces wherein the bacteria, yeast or fungi is *actinomyces viscosus, a. actinomycetemcomitans, s. gordonii, s. mutans, a. viscosus, F. nucleatum subsp. Polymorphum, p. gingivalis, p. nigrescens, staphylococcus aureus, staphylococcus, corynebacterium xerosis, c. minutissimum, propionbacterium acnes, E. coli, proteus vulgaris, kiebsiella pneumoniae, salmonella choleraesuis, pseudomonas aeruginosa, candida albicans* or *aspergillus niger.* Support for the intended use is disclosed on pages 16-20 in data from the determination of the minimum inhibitory concentration assay.

***The state of the prior art and the predictability or lack thereof in the art***

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which microbial substance by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any antimicrobial regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming a method for the antimicrobial treatment of surfaces, which comprises treating said surfaces with an antimicrobially effective amount of a compound of formula (1a). Further, applicants failed to clearly define what microbial substances can be treated against by using the claimed invention.

Applicants' claims are therefore drawn to a method for the antimicrobial treatment of surfaces against any microbial substance.

Antimicrobial chemicals include sterilants, disinfectants and fungicides. Sterilants destroy all forms of microbial life; disinfectants eliminate infectious pathogenic bacteria; sanitizers reduce microbial contaminants and fungicides destroy fungi or inanimate surfaces that are pathogenic to humans and animals. The active ingredients in the above types of products vary from alcohols, peroxides and halides to antimicrobial chemicals, such as triclosan and quaternary ammonium compounds.

For example, alcohol based hand antiseptics contain isopropanol, ethanol or n-propanol, alone or in combination. Alcohols denature proteins, which is believed to be the main mechanism of antimicrobial action. Alcohols have a wide spectrum of activity, but are less active against bacterial spores, some nonenveloped viruses and protozoan oocysts. Alcohol-based hand rubs do have activity against several nonenveloped viruses (e.g., rotavirus, adenovirus, rhinovirus and poliovirus). However, alcohol may not be effective against hepatitis A and other nonlipophilic viruses, depending on the alcohol concentration and the amount of time that viruses are exposed to the alcohol.

Another example, chlorhexidine gluconate is a cationic bisbiguanide. The mechanism of action is believed to be the disruption of cytoplasmic membranes with

subsequent precipitation of cellular material. Chlorhexidine glucomate is active against Gram-positive bacteria, is less active against Gram-negative bacteria and fungi and only exhibits minimal activity against myobacterium tuberculosis. It is not sporicidal and has in vitro activity against enveloped viruses but has less activity against nonenveloped viruses.

(See URL; http://www.cps.ca/english/statements/ID/ID06-02.htm)

***The amount of direction present and the presence or absence of working examples***

The only direction or guidance present in the instant specification is the working examples found on pages 16-20 of the specification. There are no working examples present for the treatment against viruses.

Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

***The breadth of the claims***

The breadth of the claims is drawn to a method for the antimicrobial treatment of surfaces against all types of microbial substances.

***The quantity of experimentation needed***

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what microbes out of all types such as bacteria, fungi, yeast, viruses, etc. would be benefited by claimed invention.

***The level of the skill in the art***

The level of skill in the art is high. However, due to the unpredictability in the biological art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* or *in vivo* screening to determine which compounds exhibit the desired biological activity. The specification fails to provide sufficient support of the broad use of the claimed compounds of the invention in a method for the antimicrobial treatment of surfaces. As a result necessitating one of skill to perform an exhaustive search for which microbes can be treated by what compounds of the invention in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which microbes can be treated by the compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome, for example, by amending the method claims to read on the subject matter that the Examiner has indicated is enabled by the specification.

***Claim Rejections - 35 USC § 112, 2nd paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the process that includes formula (1a) " which is dependent on claim 1 but the formula (1a) in claim 8 is broader than the formula (1a) in claim 1. The formula (1a) in claim 8 has variable $R_1$ having variable possible attachments to the phenyl ring whereas variable $R_1$ in claim 1 can only be attached at one position. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "a method for the antimicrobial treatment, deodorisation and disinfection of the skin, mucosa or hair" which is dependent on claim 9. But claim 9 is drawn only to a method for the antimicrobial treatment of surfaces and does not include "deodorisation and disinfection". There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "compound of formula (1a) is applied as a preservative" which is dependent on claim 9. But claim 9 is drawn only to a method for

the antimicrobial treatment of surfaces and does not include "a method for preservation". There is insufficient antecedent basis for this limitation in the claim.

**III. *Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626